AXONYX INC
Form 10-Q
November 09, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2005

or

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission file number: 000-25571

AXONYX INC.

(Exact name of registrant as specified in its charter)

Nevada (State or Other Jurisdiction of incorporation or organization)	**86-0883978** (IRS Employer Id. No.)

500 Seventh Avenue, 10th Floor,

New York, New York 10018

(Address of Principal Executive Offices)

Registrant s telephone number, including area code**(212) 645-7704**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). Yes x No o.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes o No x.

As of November 4, 2005, there were 53,680,721 shares of the registrant s $.001 par value Common Stock outstanding.

AXONYX INC.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

AXONYX INC.

Condensed Consolidated Balance Sheets

	September 30, 2005	December 31, 2004
ASSETS	**(unaudited)**	
Current assets:		
Cash and cash equivalents	$2,398,000	$10,091,000
Investments	60,800,000	80,500,000
Accounts receivable		229,000
Stock subscriptions receivable		2,250,000
Inventories		246,000
Other current assets	124,000	141,000
Total current assets	63,322,000	93,457,000
Property, plant and equipment, net	54,000	116,000
Investment in Oxis	5,796,000	
Technology for developed products, net		6,807,000
Patents and patents pending, net		995,000
Security deposit	25,000	19,000
	$69,197,000	$101,394,000
LIABILITIES		
Current liabilities:		
Accounts payable	$3,829,000	$6,365,000
Accrued expenses	2,776,000	2,386,000
Note payable		160,000
Total liabilities	6,605,000	8,911,000
Outside interest in Oxis		5,945,000
STOCKHOLDERS EQUITY		
Preferred stock - $.001 par value, 15,000,000 shares authorized; none issued		
Common Stock - $.001 par value, 150,000,000 and 75,000,000 shares authorized in 2005 and 2004 respectively; 53,680,721 and 53,645,518 shares issued and outstanding in 2005 and 2004 respectively	54,000	54,000
Additional paid-in capital	149,393,000	149,150,000
Unearned compensation - stock options	(48,000)	(144,000)
Accumulated comprehensive loss		(14,000)
Accumulated deficit	(86,807,000)	(62,508,000)
Total stockholders equity	62,592,000	86,538,000
Total liabilities and stockholders equity	$69,197,000	$101,394,000

See notes to the condensed consolidated financial statements

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AXONYX INC.

Condensed Consolidated Statements of Operations

(unaudited)

	Three months ended		Nine months ended	
	September 30, 2005	**2004**	**September 30, 2005**	**2004**
Revenue				
Product sales	$	$504,000	$403,000	$1,415,000
Licensing		450,000		450,000
Total revenue		954,000	403,000	1,865,000
Cost of product sales		282,000	210,000	786,000
		672,000	193,000	1,079,000
Costs and expenses:				
Research and development	5,135,000	6,054,000	21,808,000	15,888,000
General and administrative	1,018,000	1,540,000	3,894,000	6,038,000
	6,153,000	7,594,000	25,702,000	21,926,000
Loss from operations	(6,153,000)	(6,922,000)	(25,509,000)	(20,847,000)
Other income (expense)				
Interest income	586,000	379,000	1,716,000	805,000
Interest expense		(13,000)	(2,000)	(38,000)
Gain (loss) on issuance of subsidiary stock	2,000	16,000	(318,000)	71,000
Equity in loss of Oxis	(108,000)		(255,000)	
Financing fees		(164,000)		(464,000)
Foreign exchange	(14,000)	(3,000)	(95,000)	(40,000)
Total other income (expense)	466,000	215,000	1,046,000	334,000
Net loss before minority interest in subsidiary	(5,687,000)	(6,707,000)	(24,463,000)	(20,513,000)
Minority interest in loss of subsidiary		14,000	164,000	697,000
Net loss	(5,687,000)	(6,693,000)	(24,299,000)	(19,816,000)
Foreign currency translation adjustment		2,000		(32,000)
Comprehensive loss	$(5,687,000)	$(6,691,000)	$(24,299,000)	$(19,848,000)
Net loss per common share	$(0.11)	$(0.13)	$(0.45)	$(0.40)
Weighted average shares basic and diluted	**53,668,024**	**51,701,443**	**53,663,562**	**48,974,854**

See notes to the condensed consolidated financial statements

AXONYX INC.

Condensed Consolidated Statements of Changes in Stockholders Equity

(unaudited)

	Common Stock						
	Number of Shares	Amount	Additional Paid-in Capital	Unearned Compensation Stock Options	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Stockholders Equity
Balance - December 31, 2004	53,645,518	$ 54,000	$ 149,150,000	$ (144,000)	$ (62,508,000)	$ (14,000)	$ 86,538,000
Issuance of common stock options and warrants for consulting services			203,000				203,000
Issuance of common stock options			20,000				20,000
Exercise of common stock warrants and options	35,203		20,000				20,000
Amortization				96,000			96,000
Reduction from change from consolidation of Oxis to equity method						14,000	14,000
Net loss					(24,299,000)		(24,299,000)
Balance September 30, 2005	53,680,721	$ 54,000	$ 149,393,000	$ (48,000)	$ (86,807,000)	$	$ 62,592,000

See notes to the condensed consolidated financial statements

AXONYX INC.

Condensed Consolidated Statements of Cash Flows

(unaudited)

	Nine months ended September 30, 2005	2004
Cash flows from operating activities:		
Net loss	$(24,299,000)	$(19,816,000)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	423,000	657,000
Amortization of deferred financing costs		404,000
Compensation related to common stock issued for services		47,000
Compensation related to options and warrants issued for services	319,000	1,714,000
Minority interest in net loss of Oxis	(164,000)	(697,000)
Loss (gain) on issuance of subsidiary stock	318,000	(71,000)
Equity in loss of Oxis	255,000	
Changes in:		
Accounts receivable	(105,000)	(103,000)
Inventories	(1,000)	(54,000)
Other current assets	(91,000)	10,000
Other assets	(6,000)	25,000
Accounts payable	(2,217,000)	1,202,000
Accrued expenses	1,193,000	1,409,000
Accrued stock based compensation	(353,000)	(121,000)
Net cash used in operating activities	(24,728,000)	(15,394,000)
Cash flows from investing activities:		
Cash acquired in connection with Oxis acquisition		714,000
Purchase of equipment	(13,000)	(49,000)
Additions to patents	(48,000)	(240,000)
Reduction in cash due to deconsolidation of Oxis	(4,907,000)	
Purchases of investments	(49,750,000)	(131,800,000)
Proceeds from sales and maturities of investments	69,450,000	68,050,000
Costs related to Oxis acquisition		(52,000)
Net cash (used in) provided by investing activities	14,732,000	(63,377,000)
Cash flows from financing activities:		
Net proceeds from issuance of common stock and warrants	20,000	64,758,000
Net proceeds from exercise of common stock options and warrants		9,067,000
Collection of stock subscription receivable - Oxis	2,250,000	
Net proceeds from exercise of common stock options in Oxis	33,000	80,000
Net cash provided by financing activities	2,303,000	73,905,000
Net (decrease) increase in cash and cash equivalents	(7,693,000)	(4,866,000)
Cash and cash equivalents at beginning of period	10,091,000	8,830,000
Cash and cash equivalents at end of period	$2,398,000	$3,964,000
Supplemental cash flow disclosures		
Interest paid	$2,000	
Supplemental disclosure of non-cash financing activity:		
Common stock issued in connection with acquisition		$8,194,000

Unearned compensation recorded for common stock options issued		$387,000
Minority interest in subsidiary equity transactions	$22,000	

See notes to the condensed consolidated financial statements

Notes to Condensed Consolidated Financial Statements

(1) Financial Statement Presentation

The unaudited condensed consolidated financial statements of Axonyx Inc. (the Company) herein have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission (SEC) and, in the opinion of management, reflect all adjustments necessary to present fairly the financial position at September 30, 2005, and the results of operations and cash flows for the quarterly and nine month periods presented. Certain information and footnote disclosure normally included in financial statements, prepared in accordance with accounting principles generally accepted in the United States of America, have been condensed or omitted pursuant to such rules and regulations. However, management believes that the disclosures are adequate to make the information presented not misleading. These financial statements and notes thereto should be read in conjunction with the financial statements and the notes thereto for the year ended December 31, 2004, included in the Company s Form 10-K filing. The results for the interim periods are not necessarily indicative of the results for the full fiscal year. Certain prior year amounts have been reclassified to conform to current year presentation.

Principles of consolidation

The consolidated financial statements include the accounts of Axonyx Europe, B.V., a wholly owned subsidiary organized in The Netherlands. The financial statements also include the accounts of OXIS International Inc. (OXIS) from the acquisition date of January 15, 2004 when the Company acquired approximately 52% of the common voting stock of OXIS through February 28, 2005. The Company s ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS, however, the accounts of OXIS continued to be consolidated as the Company controlled the board of directors through a majority of the OXIS board seats. On February 28, 2005 OXIS announced that Mr. Steven T. Guillen had joined OXIS as President and Chief Executive Officer and as a member of the OXIS Board of Directors. Consequently the Company no longer had a majority of the seats on the OXIS Board, and, beginning March 1, 2005, OXIS is no longer consolidated but rather accounted for using the equity method.

The outside interest on the balance sheet as of December 31, 2004 includes the approximately 66% of OXIS that is not owned by the Company. The outside interest also includes a portion of the carrying value of technology for developed products, net attributable to the reduction in the Company s ownership in OXIS from approximately 52% to approximately 34% as of December 31, 2004.

(2) Investment in OXIS International, Inc.

The Company s investment in OXIS at September 30, 2005 is determined under the equity method of accounting. In moving from the full consolidation of OXIS at December 31, 2004 to the equity method beginning in March 2005, the Company determined that a correction was required in the calculation of the gain on subsidiary stock under SEC Staff Accounting Bulletin No. 51. The gain resulted from the issuance of shares by OXIS at December 31, 2004 in connection with a private placement financing. The correction has been effected by a $398,000 reduction in the carrying value of the investment in OXIS in March 2005 with a corresponding reduction in the loss on issuance of subsidiary stock for the period then ended.

The correction has been reflected in the quarter ended March 31, 2005 and the results for the nine months ended September 30, 2005 in accordance with the provisions of Accounting Principles Board Opinion No. 28, Interim Financial Reporting, as it is not material to either the 2004 results of operations, the estimated full year 2005 results of operations or to the trend of operations.

The Company owns approximately 14 million common shares of OXIS International Inc. with a carrying value at September 30, 2005 of $5,796,000. Oxis is traded on the bulletin board (OXIS.OB) with relatively little trading volume. At September 30, 2005, the market value of these shares was $0.37 per share ($5.2 million).

(3) Acquisition of OXIS International, Inc.

On January 15, 2004, the Company entered into agreements to acquire approximately 52% of the outstanding voting stock of OXIS. OXIS is a biopharmaceutical company engaged in the development of research diagnostics, nutraceuticals and therapeutics in the field of oxidative stress. Under the terms of separate agreements entered into with several holders of OXIS common stock, the Company acquired an aggregate of approximately 14

million shares of OXIS stock, in consideration for the issuance of an aggregate of approximately 1.6 million shares of the Company s unregistered common stock, which was registered in May 2004. Marvin S. Hausman, MD, the Company s former Chairman and former Chief Executive Officer, owned 1,162,532 shares of OXIS common stock, representing at the time of the acquisition approximately 4% of OXIS voting stock. Those shares of OXIS s common stock were not acquired.

The aggregate purchase price was $8,246,000, which includes the fair value of the Company s common shares that were issued as consideration and transaction costs.

The allocation of the cost of the acquisition is a follows:

Current assets	$1,492,000
Equipment	41,000
Technology and developed products	7,622,000
Patents and other assets	765,000
Current liabilities	(1,039,000)
Minority interest	(635,000)
Deferred tax liability (1)	(3,011,000)
Deferred tax liability (2)	3,011,000
	$8,246,000

(1) Represents the tax effect of the excess of the financial statement basis over the tax basis for acquired technology for developed products.
(2) Represents the tax benefit of OXIS net operating loss carry forward and deductible temporary differences recognized as an offset against the deferred tax liability attributable to the acquired technology for developed products.

The following proforma information gives effect to the acquisition as if it had occurred on the first day of the quarter and nine months ended September 30, 2004.

	Three months ended Sept. 30, 2004	**Nine months ended Sept. 30, 2004**
Total revenues	$ 954,000	$ 1,954,000
Net loss including minority interest in subsidiary	(6,707,000)	(20,630,000)
Net loss	(6,693,000)	(19,893,000)
Basic and diluted net loss per common share	(0.13)	(0.40)

(4) Stock-based Compensation

The Company follows the intrinsic value based method in accounting for stock-based employee compensation under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations. The Company has adopted the disclosure-only provisions of Statement of Financial Accounting Standard (SFAS) No. 123, Accounting for Stock-Based Compensation and SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. The Company follows the fair value based method for awards to non-employees. Effective January 1, 2006, the Company will adopt SFAS No. 123R Share Base Payment which requires all share based payments to employees, including stock options, to be recognized as expense based on their fair value.

The following table illustrates the effect on net loss and loss per share if the fair value based method had been applied to all awards:

	Three months ended Sept. 30,		Nine months ended Sept. 30,	
	2005	2004	2005	2004
Reported net loss attributable to common stockholders	$(5,687,000)	$(6,693,000)	$(24,299,000)	$(19,816,000)
Stock-based employee compensation included in net loss	32,000	33,000	116,000	210,000
Stock-based employee compensation determined under the fair value based method	(511,000)	(636,000)	(1,821,000)	(1,879,000)
Pro forma net loss	$(6,166,000)	$(7,296,000)	$(26,004,000)	$(21,485,000)
Loss per common share attributable to common stockholders (basic and diluted):				
As reported	$(0.11)	$(0.13)	$(0.45)	$(0.40)
Pro forma	$(0.11)	$(0.14)	$(0.48)	$(0.44)

(5) Operating Segments

The Company is organized into two reportable segments: Axonyx and OXIS. While OXIS has historically been organized into two reportable segments (health products and therapeutic development), Oxis currently manages its operations in one segment in order to better monitor and manage its basic business: the development of research diagnostics, nutraceutical and therapeutic products. Beginning March 1, 2005, the Oxis segment reflects the Company s share of Oxis losses under the equity method.

The following table presents information about the Company s two operating segments:

	Axonyx Inc.	Oxis Int l Inc.	Total
Quarter ended September 30, 2005			
Segment loss	$ (5,579,000)	$ (108,000)	$ (5,687,000)
Quarter ended September 30, 2004			
Revenue including minority interest		954,000	954,000
Segment loss	$ (6,466,000)	$ (227,000)	$ (6,693,000)
Nine months ended September 30, 2005			
Revenue including minority interest		$ 403,000	$ 403,000
Segment loss	$ (23,865,000)	(434,000)	$ (24,299,000)
Nine months ended September 30, 2004			
Revenue including minority interest		$ 1,865,000	$ 1,865,000
Segment loss	$ (18,226,000)	$ (1,590,000)	$ (19,816,000)
Segment assets including minority interest at Sept. 30, 2004	$ 87,002,000	$ 9,658,000	$ 96,660,000

(6) Related Party Transaction

In June 2004, Axonyx Inc., which then had a controlling interest in OXIS International, Inc., loaned OXIS $1.2 million, which was eliminated in consolidation as of December 31, 2004. Pursuant to its terms, OXIS repaid the loan with accrued interest in January 2005.

(7) Developments with SERONO International SA

Effective as of May 17, 1999, Axonyx Inc. entered into a Development Agreement and Right to License (the Development Agreement) with Applied Research Systems ARS Holding N.V., a wholly owned subsidiary of Serono International, SA (Serono). Under the Development Agreement, the Company granted to Serono an exclusive right to license its patent rights and know-how regarding its amyloid inhibitory peptide (AIP) and prion inhibitory peptide (PIP) technology.

In 2000, the Company and Serono finalized a definitive Licensing Agreement, pursuant to which the exclusive worldwide patent rights to the Axonyx s AIP and PIP technology were granted to Serono. The Company received a nonrefundable, noncreditable license fee of $1.5 million, which was recognized as revenue since the Company is not responsible for any ongoing research and development activities or any other services with respect to this arrangement and it represented the culmination of a separate earnings process.

In April 2003, Axonyx received a milestone payment of $1,000,000 from Serono under the terms of the license agreement, which was triggered when Serono initiated a Phase I clinical trial with a patented product.

In July 2004, we signed a non-binding Memorandum of Understanding (MOU) for the research and joint development of therapeutic compounds including the Amyloid Inhibitory and Prion Inhibitory Peptides, and diagnostic technologies in the field of protein mis-folding disorders such as Parkinson s Disease, Down s Syndrome, Diabetic disorders, Lou Gehrig s Disease, Alzheimer s Disease, Transmissible Spongioform Encephalopathies (TSE s), i.e. Mad Cow Disease (BSE), and Creutzfeldt Jakob Disease new variant (CJDnv).

Since the signing of the MOU, the parties had been negotiating the terms of definitive agreements. As part of its business strategy going forward, Axonyx has now elected not to proceed with the proposed joint venture and as it is the Company s current understanding that Serono will not be pursuing development of the licensed technologies, Axonyx is in discussions to seek a return to Axonyx of all patent rights and related know how that was licensed to Serono.

(8) Shareholder Rights Plan

The Company adopted a shareholder rights plan on May 16, 2005. The shareholder rights plan is designed to protect shareholders in realizing fair value and equal treatment in the event of an attempted takeover of the

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Company and to protect the Company and its shareholders against coercive takeover tactics. The plan was not adopted as a result of any existing or proposed potential takeover threat.

Under the terms of the plan, Axonyx distributed one purchase right for each share of common stock outstanding to shareholders at the close of business on May 27, 2005. Axonyx will not issue a separate certificate for the rights unless and until they become exercisable.

Each right entitles the holder to purchase from the Company one one-thousandth of a share of a new series of participating preferred stock at an initial purchase price of $15. The rights will become exercisable and will detach from the common stock for a specified period after any person or group, without the approval of the Company s board of directors, has become the beneficial owner of, or commences a tender offer or exchange offer for, 15% or more of the then outstanding shares of Axonyx common stock (subject to certain exceptions).

(9) Reclassification

During the quarter ended September 30, 2005 the Company has reclassified the majority of what was previously classified as cash and cash equivalents to investments. The Company follows FASB 115 in determining the appropriate classification for cash equivalents and investments. The Company has invested in auction rates securities (ARS) that are held as investments available-for-sale. After the initial issuance of these securities, the interest rate is reset periodically. We have invested in ARS that reset as to interest rate every 28 days.

The Company has determined that auction rate securities should be classified as investments because the stated or contractual maturities are generally 20 to 30 years. From an economic viewpoint, these securities are priced and traded as short-term investments because of the interest rate reset feature. Accordingly, the Company has reclassified all such auction rate securities as investments for all periods presented.

(10) Recent Developments

As further described in Item 2 below under The Phenserine Development Program, the Company has determined not to commit further resources to the development of Phenserine.

Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

This Form 10-Q contains forward-looking statements, as defined in the Private Securities Litigation Reform Act of 1995 that are based on current expectations, estimates and projections. Statements that are not historical facts, including statements about our beliefs and expectations, are forward-looking statements. These statements involve potential risks and uncertainties; therefore, actual results may differ materially. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date on which they were made. We do not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

Specifically, with respect to our drug candidates Phenserine, Posiphen and BisNorCymserine, Axonyx cannot assure that: any preclinical or clinical trials, whether ongoing or conducted in the future, will prove successful, and if successful, that the results could be replicated; safety and efficacy profiles of any of its drug candidates will be established, or if established, will remain the same, be better or worse in future clinical trials, if any; pre-clinical results related to cognition and the regulation of beta-APP will be sustained by ongoing or future clinical trials, if any, or that any of its drug candidates will be able to slow the progression of Alzheimer s disease; any of its drug candidates will support an NDA filing, will be approved by the FDA, or if approved, will prove competitive in the market; Axonyx will be able to successfully out-license any of its drug candidates; Axonyx will be able to successfully in-license any additional compounds, or that Axonyx will obtain the necessary financing to support its drug development program.

We refer you to our report on form 10-K for the year ended December 31, 2004 filed with the SEC, where these risks and others are more fully described.

We do not undertake to discuss matters relating to our ongoing clinical trials or our regulatory strategies beyond those which have already been made public or discussed herein.

Overview of our Company

We are a biopharmaceutical company, specializing in central nervous system (CNS) neurodegenerative diseases, engaged in the business of acquiring the patent rights to clinical stage compounds, compounds with strong proof of concept data and compounds ready for proof of concept validation with convincing scientific rationale, or potentially another company with similar rights. We further develop and add value to these compounds and then

seek to out-license or partner them when we believe it business prudent. We have acquired patent rights to three main classes of therapeutic compounds designed for the treatment of Alzheimer s disease (AD), Mild Cognitive Impairment, and related diseases. We have acquired patent rights to a class of potential therapeutic compounds designed for the treatment of prion related diseases, which are degenerative diseases of the brain that are thought to be caused by an infectious form of a protein called a prion. Prions, unlike viruses, bacteria and fungi, have no DNA and consist only of protein. Such diseases include Creutzfeldt Jakob Disease, new variant in humans, Bovine Spongiform Encephalopathy (BSE or Mad Cow Disease) in cows, and Scrapies disease in sheep. We have licensed these patent rights separately from New York University and from the National Institutes of Health/National Institute on Aging (via a sublicense). We also have co-inventorship rights to a patent application regarding a therapeutic compound named Posiphen designed for the treatment of Alzheimer s disease progression.

Our mission is to be a leading biopharmaceutical company that develops products and technologies to treat central nervous system disorders. Our initial business strategy has been focused primarily on three compounds in development for Alzheimer s disease. These are:

Phenserine A symptomatic and disease progression treatment of mild to moderate AD.
Posiphen A disease progression treatment for AD
Bisnorcymserine (BNC) A symptomatic treatment of severe AD.

Our current business strategy includes identifying and seeking to in-license potential compounds or partner with companies to expand our product development portfolio.

Phenserine is an inhibitor of acetylcholinesterase for the potential treatment of mild to moderate AD. Acetylcholinesterase is an enzyme active in the nerve synapse that degrades the neurotransmitter acetylcholine in the brain and other tissues of the body. Acetylcholinesterase inhibitors are drugs designed to selectively inhibit acetylcholinesterase. Acetylcholine is a chemical substance that sends signals between nerve cells, called neurotransmission, and is therefore called a neurotransmitter. Neurotransmitters are secreted by neurons, or nerve cells, into the space between neurons called the synapse. Acetylcholine is a primary neurotransmitter in the brain, and is associated with memory and cognition.

Posiphen is a compound that appears to decrease the formation of the beta amyloid precursor protein (beta-APP) and amyloid with potential applications in the treatment of AD. Posiphen is the positive isomer of Phenserine. As such, it appears to affect the messenger RNA of beta-APP as well as inhibit beta secretase whereby beta amyloid levels, in preclinical animal models, are reduced.

Bisnorcymserine is a butyrylcholinesterase inhibitor. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase is an enzyme that is normally found widely in the body and butyrylcholine appears to play a relatively increasingly important role in advancing AD. Inhibition of the enzyme may prove valuable in the treatment of severe AD.

The Phenserine Development Program

The Company s drug furthest along in development, Phenserine, is a third generation acetylcholinesterase inhibitor, which progressed to late stage clinical trials. The results of the 1st Phase III trial were announced on February 7, 2005 and interim results from the Phase IIb beta amyloid trial were announced on March 11, 2005. The Company announced a second interim analysis of the Phase IIb trial on July 26, 2005. Subsequently, the Company analyzed data from additional patients in that trial.

Overall, the results from the Phase III trial did not show statistically significant improvements over placebo for the protocol s primary endpoints following 26 weeks of treatment. We have evaluated the results, and following recommendations from our Scientific Advisory Board and Safety Steering Committee, we have curtailed the Phenserine clinical program going forward. The Phenserine results from the 1st Phase III trial demonstrated a consistent positive trend on primary and secondary domains in the symptomatic management of Alzheimer s disease. However, there was no statistically significant efficacy in cognition, global function and activities of daily living. That may in part have been caused by the minimal decline over the 26 weeks in the placebo group. The March 11, 2005 interim analysis of the results from our Phase IIb beta amyloid trial, while not meant to show significance, showed a consistent trend towards beta amyloid reduction with the 15mg twice daily doses. While the

second interim analysis announced on July 26, 2005 appeared again to confirm that Phenserine may have an impact on the levels of beta amyloid, there is still insufficient evidence due to the variability of the data to draw definitive conclusions.

On September 20, 2005, the Company announced the top line results of an analysis of the combined data from its two curtailed Phase III clinical trials (AX-CL-09/010) with Phenserine, in development for mild to moderate Alzheimer s disease (AD). The combined data included 255 (instead of the originally planned 900) mild to moderate AD patients who received 12 weeks of treatment (instead of the originally planned 26 weeks). Analysis of the efficacy endpoints, as measured by the Alzheimer s disease Assessment Scale, cognitive subscale (ADAS cog) and Clinical Interview Based Impression of Change with caregiver input (CIBIC+), did not demonstrate a statistically significant benefit of Phenserine treatment over placebo. Patient recruitment for these studies had been halted and the planned 26-week treatment period shortened based on previously released results of a 375-patient trial (AX-CL-06) which showed no statistically significant differences between Phenserine and placebo. There were no safety or tolerability concerns associated with Phenserine treatment.

We have now evaluated our whole Phenserine development program following the results of the first Phase III results announced in February and March 2005, the results of the curtailed second and third Phase III trials that were subsequently combined, in September 2005, and the interim analysis of the beta amyloid trial announced in March and July 2005.

Based on our analysis, we have determined not to commit further resources to the development of Phenserine given our existing financial resources, anticipated time to market and potential market environment at the time of potential product launch. Positive signals were observed in all our trials to date, including the interim analyses of the Phase IIb beta amyloid trial. However, none of these trials achieved statistical significance for the primary end points. Therefore, we have decided to accelerate our marketing package for the out-licensing of Phenserine. Our trials to date on Phenserine, including extensive preclinical studies, have provided us with a comprehensive set of data. Utilizing this data we will explore opportunities for out-licensing Phenserine to a company willing to commit the financial resources necessary to investigate the reformulation of Phenserine to a sustained or extended release formulation rather than the immediate release formulation used in the recently completed or curtailed trials, and to undertake the necessary further clinical trials. We will not incur any additional development expenses for Phenserine beyond those expenses needed to close the ongoing activities in an orderly fashion.

The Posiphen Development Program

Posiphen has been shown to lower beta amyloid precursor protein (beta-APP) levels in pre-clinical studies. The primary mechanism of action results in a dose dependent reduction of beta amyloid, which may result in slowing AD progression. The initial pre-clinical side effect rates potentially allow for higher clinical doses. On August 1, 2005 the Company announced that the US Food and Drug Administration (FDA) has approved its investigational new drug (IND) application allowing Phase I clinical testing of Posiphen. The first Phase I clinical study commenced in August 2005 and will primarily evaluate the safety of Posiphen in healthy volunteers. This study is ongoing.

The Bisnorcymserine Development Program

BisNorCymserine (BNC) is a highly selective butyrylcholinesterase inhibiter. Butyrylcholinesterase is found in high concentration in the plaques taken from individuals who have died from AD. Butyrylcholinesterase appears to have an increasing role with advancing Alzheimer s disease and its primary mechanism of action results in a dose dependent reduction of acetylcholine. The initial pre-clinical side effect rate potentially allows higher clinical doses. A secondary mechanism of action is associated with dose dependent reductions of beta APP and amyloid beta. BNC, the lead compound from our butyrylcholinesterase family, is currently in full pre-IND development and we plan an IND submission in first quarter 2006 followed by the potential to initiate Phase I clinical trials thereafter.

Other Pertinent Information

In December 2000, the Company incorporated Axonyx Europe BV, a wholly owned subsidiary, in the Netherlands. Gosse Bruinsma, M.D., currently the President and Chief Executive Officer of Axonyx Inc., is also the

President of Axonyx Europe BV. To date the majority of our clinical development activities and a significant amount of our pre-clinical development activities are carried out in Europe. The Axonyx Europe BV office manages, directs, and controls these activities. Axonyx Europe BV explores and pursues in-licensing and out-licensing opportunities for the Company s licensed technologies and facilitates communication with the Company s European shareholders.

In June 2005, the Company appointed Paul Feuerman as its General Counsel. Mr. Feuerman is a founding member of Pharm Advisors LLC, a consulting firm serving pharmaceutical and biopharmaceutical companies. Formerly, he was Executive Vice President and General Counsel of Schein Pharmaceutical Inc., a New York Stock Exchange listed specialty pharma/generics company.

We have incurred negative cash flows from operations since the inception of the Company in 1997. Our net losses for the three fiscal years ended 2002, 2003 and 2004 were $6,256,000, $8,106,000 and $28,780,000 respectively, and our net loss for the nine months ended September 30, 2005 was $24,299,000. We have no products available for sale and we do not expect to have any products commercially available for several years, if at all.

Axonyx Inc. was incorporated in Nevada on July 29, 1997. Our principal executive offices are located at 500 Seventh Avenue, 10th Floor, New York, New York 10018, and our telephone number is (212) 645-7704.

RESULTS OF OPERATIONS

Revenues

The Company had no revenue for the quarter ended September 30, 2005 and $954,000 for the quarter ended September 30, 2004. The Company had revenue of $403,000 and $1,865,000 for the nine months ended September 30, 2005 and 2004, respectively. Revenue in 2005 and 2004 was derived from the sale of research assays and fine chemicals at OXIS. In 2004, included in revenue is $450,000 Oxis received in licensing income. The reduction in revenue for the quarter and nine months ended September 30, 2005 from prior year levels results from the fact that OXIS operations are no longer being consolidated with our results effective March 1, 2005 as discussed in Note 1 to the condensed consolidated financial statements.

Costs of Sales

The Company s costs of sales were entirely related to its subsidiary, OXIS. The percentage of cost of sales for the nine months ended September 30, 2005 and 2004 were 52% and 56% respectively.

Research and Development

Research and development expenses were $5,135,000 and $6,054,000 for the quarters ended September 30, 2005 and 2004, respectively. Research and development expenses were $21,808,000 and $15,888,000 for the nine months ended September 30, 2005 and 2004 respectively. In 2004, the Company was conducting both a Phase IIb and Phase III trial for Phenserine, its lead drug compound. In 2005, two additional Phase III trials were underway, as well as continuing costs associated with the earlier two trials. This accounts for the majority of the increase in research and development expenses. Additionally, Phenserine preclinical studies in carcinogenicity and absorption, distribution, metabolism and excretion (ADME) decreased by $1,426,000 from the same nine month period in 2004. Posiphen preclinical costs increased by $1,815,000 over the prior nine month period as the Company advances Posiphen preclinical testing. The nine month period also includes $423,000 in costs incurred with the Company s third compound, BisNorCymserine.

Sales, General and Administrative

Sales, general and administrative expenses were $1,018,000 and $1,540,000 for the quarters ended September 30, 2005 and 2004, respectively. Sales, general and administrative expenses were $3,894,000 and $6,038,000 for the nine months ended September 30, 2005 and 2004, respectively. Non-cash charges relating to stock option grants to consultants were $1,622,000 lower in the nine months ended September 30, 2005 than the nine months ended September 30, 2004. Professional fees were $2,055,000 compared to $1,050,000 in the nine months ended September 30, 2005 and 2004, respectively. The increase in professional fees is primarily attributed to utilization of additional outside counsel, patent filing costs, legal costs related to class action securities litigation,

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Sarbanes Oxley compliance and board member fees. The additional reduction in sales, general and administrative expenses for the quarter and nine months ended September 30, 2005 from prior year levels results from the fact that OXIS operations are no longer consolidated with our results effective March 1, 2005 as discussed in Note 1 to the condensed consolidated financial statements.

Other Income (Expense)

Interest income was $586,000 and $379,000 for the quarters ending September 30, 2005 and 2004, respectively. Interest income was $1,716,000 and $805,000 for the nine months ended September 30, 2005 and 2004, respectively. The increase reflects the higher cash and cash equivalent balances held in 2005 resulting from the private placements completed in 2004 and a rise in short term yields.

Foreign exchange for the quarters ended September 30, 2005 and 2004 were losses of $14,000 and $3,000, respectively. Foreign exchange losses of $95,000 and $40,000 were incurred for the nine months ended September 30, 2005 and 2004 respectively. The loss in 2005 reflects the strength of the Euro against the US dollar in 2005.

Loss on issuance of subsidiary stock was $318,000 net for the nine months ended September 30, 2005. This net loss on issuance of subsidiary stock results from common stock equity transactions in OXIS and the adjustment discussed in Note 2 of the Notes to Condensed Consolidated Financial Statements.

Equity in loss of OXIS of $255,000 reflects the Company s proportional share of OXIS losses from March 1, 2005 forward under the equity method of accounting.

Interest expense reflects the cost of borrowing incurred by OXIS in obtaining temporary short term financing.

Net Loss

The Company experienced net losses of $5,687,000 ($0.11 per share-basic and diluted) and $6,693,000 ($0.13 per share-basic and diluted) for the quarters ended September 30, 2005 and 2004, respectively. The Company experienced net losses of $24,299,000 ($0.45 per share-basic and diluted) and $19,816,000 ($0.40 per share-basic and diluted) for the nine months ended September 30, 2005 and 2004 respectively. The increase in the net loss is primarily due to the expense of the Phase IIB and Phase III clinical trials for Phenserine and initiation of the second and third Phase III clinical trials.

LIQUIDITY AND CAPITAL RESOURCES

As of September 30, 2005 we had $63,198,000 in cash, cash equivalents and investments, and $56,717,000 in working capital. We do not have any available lines of credit. Since inception we have financed our operations from private placements of equity securities, the exercise of common stock purchase warrants, license fees, interest income and loans from a shareholder.

Net cash used in operating activities for the nine months ended September 30, 2005 was $24,728,000 resulting primarily from a net loss of $24,299,000 and a decrease in accounts payable of $2,217,000 partially offset by an increase in accrued expenses of $1,193,000.

Net cash provided by investing activities was $14,732,000 for the nine months ended September 30, 2005 resulting principally from investment sales and maturities in excess of investment purchases and the deconsolidation of OXIS of $4,907,000.

Net cash provided by financing activities for the nine months ended September 30, 2005 was $2,303,000. In January 2005 OXIS received $2,250,000 of stock subscriptions receivable from a December 31, 2004 private placement.

We plan to finance our needs principally from the following:

- our existing capital resources and interest earned on that capital; and
- future private placement financing or other equity financings.

We believe that we have sufficient capital resources to finance our plan of operation at least through December 31, 2006. However, as this is a forward-looking statement, and there may be changes that could consume

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available resources significantly before such time. Our long term capital requirements and the adequacy of our available funds will depend on many factors, including the eventual contract costs of undertaking large later stage clinical trials with any of our compounds under development, the potential cost of acquiring or developing compounds that we may license in, regulatory delays, patent costs for filing, prosecuting, maintaining and defending our patent rights, and defending our current class action securities litigation, among others.

We may be periodically seeking potential equity financing, sub-licensing and other collaborative arrangements that may generate additional capital for us in order to support our research and development activities. We cannot assure you that we will generate sufficient additional capital or revenues, if any, to fund our operations beyond December 31, 2006, that any future equity financings will be successful, or that other potential financings through bank borrowings, debt or equity offerings, or otherwise, will be available on acceptable terms or at all.

Critical Accounting Policies and Estimates

This discussion and analysis of our financial condition and results of operations are based on our financial statements that have been prepared under accounting principles generally accepted in the United States of America. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires our management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could materially differ from those estimates. We have disclosed all significant accounting policies in note B to the financial statements included in our annual report on Form 10-K for the year ended December 31, 2004. Our critical accounting policies are:

Principles of consolidation: The consolidated financial statements include the accounts of Axonyx Europe, B.V., a wholly owned subsidiary organized in The Netherlands. The financial statements also include the accounts of OXIS from the acquisition date of January 15, 2004 when the company acquired approximately 52% of the common voting stock of OXIS. The Company s ownership in OXIS was reduced to 34% on December 31, 2004 as the result of a third party financing by OXIS. Although the Company has less than a majority ownership at December 31, 2004, the accounts of OXIS continued to be consolidated as the Company then controlled the board of directors of OXIS. Effective March 1, 2005 the Company no longer controls the OXIS board. Thus the financial statements of OXIS have been consolidated through February 28, 2005 and equity method accounting has been applied beginning March 1, 2005. All intercompany balances and transactions have been eliminated in consolidation.

Revenue recognition: We defer recognition of revenue from fees received in advance unless they represent the culmination of a separate earnings process. Such deferred fees are recognized as revenue over the term of the arrangement as they are earned, in accordance with the agreement. License fees represent the culmination of a separate earnings process if they are sold separately without obligating us to perform research and development activities or other services. Right to license fees is recognized over the term of the arrangement. Nonrefundable, non-creditable license fees that represent the culmination of a separate earnings process are recognized upon execution of the license agreement. Revenue from the achievement of milestone events stipulated in the agreements will be recognized when the milestone is achieved. Royalties will be recognized as revenue when the amounts earned become fixed and determinable.

Research, development costs: Research and development costs are expensed as incurred.

Stock-based compensation: We account for stock-based employee compensation under the intrinsic value method prescribed by Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees , and related interpretations. We have adopted the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation and SFAS No. 148, Accounting for Stock-Based Compensation - Transition and Disclosure , which was released in December 2002 as an amendment of SFAS No. 123. We follow the fair value based method of accounting for awards to non-employees.

Accounting for Investment in OXIS: Beginning March 1, 2005, the Company accounts for its investment in OXIS under the equity method of accounting, as prescribed by Accounting Principals Board Opinion No. 18 The Equity Method of Accounting for Investments in Common Stock . Pursuant to APB No. 18 a loss in value of an investment which is other than a temporary decline should be recognized the same as a loss in value of other long-term assets.

Accounting for stock sales by subsidiary: The Company accounts for stock sales by a subsidiary (OXIS) in accordance with SEC Staff Accounting Bulletin No. 51. Sales of shares by OXIS result in a change in the carrying value of the investment in OXIS.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We have foreign currency accounts that are exposed to currency exchange risk. These foreign currency accounts have been utilized to fund the operations of our wholly owned subsidiary, Axonyx Europe, based in The Netherlands. We had a net foreign exchange loss of $95,000 for the nine months ended September 30, 2005 and a loss of $40,000 for the nine months ended September 30, 2004. If the foreign currency rates were to fluctuate by 10% from rates at September 30, 2005 and 2004, the effect on our financial statements would not be material. However, there can be no assurance there will not be a material impact in the future. During 2003, we adopted a policy to limit the purchase of foreign currencies to the amounts necessary to cover firm contractual commitments in foreign currencies for the forward six months. However, as long as we continue to fund our foreign operations and activities, we will be exposed to some currency exchange risks. The majority of our ongoing clinical trials are being conducted in Europe.

We consider our investments in money market accounts, short term commercial paper and time deposits as cash and cash equivalents. The carrying values of these investments approximate fair value because of the short maturities (three months or less) of these instruments and accounts. Therefore, changes in the market s interest rates do not affect the value of the investments as recorded by us.

We do not enter into or trade derivatives or other financial instruments or conduct any hedging activities.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this quarterly report on Form 10-Q. Based on this evaluation, our principal executive officer and principal financial officer concluded that these disclosure controls and procedures are effective and designed to ensure that the information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the requisite time periods.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the system are met and cannot detect all deviations. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud or deviations, if any within the Company have been detected. While we believe that our disclosure controls and procedures have been effective, in light of the foregoing, we intend to continue to examine and refine our disclosure control and procedures to monitor ongoing developments in this area.

Changes in Internal Controls

There was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) identified in connection with the evaluation of our internal control performed during our last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II OTHER INFORMATION

Item 1. Legal Proceedings.

Axonyx, Dr. M. Hausman, Dr. G. Bruinsma and Mr. S. Colin Neill have been named as defendants in nine purported shareholder class action lawsuits commencing in February 2005 alleging violations of federal securities laws, one of which has been voluntarily dismissed. Eight of those lawsuits remain pending in the U.S. District Court for the Southern District of New York and assert claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5 thereunder on behalf of a class of purchasers of our common stock during the period from June 26, 2003, through and including February 4, 2005 (the Class Period). The complaints allege generally

that the defendants knowingly or recklessly made false or misleading statements during the Class Period regarding the prospects of a trial regarding the effectiveness of Phenserine in treating mild to moderate Alzheimer s disease, which had the effect of, among other things, artificially inflating the price of our shares. The complaints seek unspecified damages. Axonyx and the other defendants have not yet filed their responses to these purported class actions.

In addition to the federal securities cases, a purported shareholder derivative lawsuit was filed in New York State Supreme Court in March 2005 against Marvin S. Hausman, Gosse B. Bruinsma, S. Colin Neill, Louis G. Cornacchia, Steven H. Ferris, Gerard J. Vlak, Ralph Snyderman, Michael A. Griffith and Axonyx (as a nominal defendant). The plaintiff in the derivative action alleges, among other things, that the defendants named in that case breached their fiduciary duties, wasted corporate assets and were unjustly enriched. The allegations in the derivative action arise from the same and related purported facts as those alleged in the federal securities actions. On July 29, 2005, we and the other named defendants moved to dismiss the shareholder derivative suit with prejudice.

We believe the complaints are without merit and intend to defend these lawsuits vigorously. However, we cannot assure you that we will prevail in these actions, and, if the outcome is unfavorable to Axonyx, our reputation, operations and share price could be adversely affected.

Item 6. Exhibits.

Number	Exhibits
10.1	Form of Change of Control Agreement between Axonyx Inc. and Paul Feuerman, dated as of September 12, 2005 (incorporated by reference to exhibit 99.1 to the registrant s Current Report on Form 8-K filed September 6, 2005).
31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(a) and 15d-14(a), adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Dated November 8, 2005.

AXONYX INC.

By: /s/ Gosse B. Bruinsma, M.D.

Gosse B. Bruinsma, M.D.
President and Chief Executive Officer

By: /s/ S. Colin Neill

S. Colin Neill
Chief Financial Officer,
Secretary and Treasurer
(Principal Financial and Accounting Officer)